Arvelle Announces European Medicines Agency Acceptance of the Marketing Authorization Application (MAA) for Cenobamate

The MAA seeks authorisation for the adjunctive treatment of focal-onset seizures in adult patients with epilepsy

Zug, Switzerland, 26 March 2020 - Arvelle Therapeutics, an emerging biopharmaceutical company focused on bringing innovative treatments to patients suffering from CNS disorders, today announces that the European Medicines Agency (EMA) has accepted the marketing authorization application (MAA) for cenobamate for the adjunctive treatment of focal-onset seizures in adults with epilepsy. Validation of the MAA confirms that the application is complete and marks the start of the assessment process.

The MAA is supported by data from two randomized, double-blind, placebo-controlled studies, and a large, international, multi-centre open-label safety study investigating cenobamate as an adjunctive therapy in adult patients with focal-onset seizures.

Arvelle Therapeutics licensed the exclusive rights to develop and commercialize cenobamate in Europe from SK Biopharmaceuticals Co., Ltd. and the data supporting the MAA was generated from SK Life Science, Inc.'s (a subsidiary of SK Biopharmaceuticals) global clinical trial program. In November 2019, SK life science received approval from the U.S. Food and Drug Administration (FDA) for cenobamate tablets as a treatment for focal-onset seizures.

Commenting on the news, Mark Altmeyer, President and CEO of Arvelle Therapeutics, said: *"The acceptance of the MAA marks an important milestone for Arvelle. Our filing, together with the FDA's recent approval of cenobamate in the US, makes us believe that cenobamate could provide an effective treatment option for the many focal-onset seizure patients with epilepsy who are still experiencing uncontrolled seizures. We will continue to work in close collaboration with the EMA in order to progress this application and bring cenobamate to patients across Europe as soon as possible."*

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About Arvelle Therapeutics

Arvelle Therapeutics is an emerging biopharmaceutical company focused on bringing innovative solutions to patients suffering from CNS disorders. Arvelle is responsible for the development and commercialization of cenobamate, an investigational antiepileptic drug, in the European market. Arvelle is headquartered in Switzerland and received start-up financing of $207.5 million, one of the largest initial financing commitments for a European-focused biopharmaceutical company, with investments from a global syndicate including NovaQuest Capital Management, BRV Capital Management, LSP, H.I.G. BioHealth Partners, Andera Partners, F-Prime Capital and KB Investments. More information is available at http://arvelletx.com.

About Cenobamate

Cenobamate was discovered by SK Biopharmaceuticals and SK life science and is a new FDA-approved anti-epileptic drug (AED) for the treatment of partial-onset seizures in adults. Cenobamate is approved and will be commercially available in the U.S. under the trademark XCOPRI®. In early 2019, SK Biopharmaceuticals entered into an exclusive licensing agreement with Arvelle Therapeutics to develop and commercialize cenobamate in Europe.

Cenobamate is believed to work through a unique, dual, complementary mechanism of action: Enhancing inhibitory currents through positive modulation of GABAA receptors at a non-benzodiazepine binding site, and decreasing excitatory currents by both inhibiting the persistent sodium current and enhancing the inactivated state of voltage-gated sodium channels.

Long term data of cenobamate is being further studied in the open-label extensions of the double-blind placebo control trials as well as the open-label safety study in adults with focal-onset seizures. Additionally, cenobamate is being assessed in an ongoing randomized, double-blind, placebo-controlled trial evaluating its safety and efficacy as adjunctive therapy in patients with primary generalized tonic-clonic seizures (NCT03678753).